K092056

5 510(K) SUMMARY

OCT - 1 2009

Date:	October 30, 2008
510(k) owner's name:	Optomed Oy
Address:	Hallituskatu 13-17 D 96, 90100 Oulu, Finland
Name of contact person:	Mr. Jeffrey Rongero, UL RTP OFFICE COORDINATOR
Phone:	919 549 1922
Device name:	Trade name: Optomed Smartscope M3-1 EY1 Common/usual name: Digital Ophthalmoscope Classification name: camera, ophthalmic, ac-powered (21 CFR 886.1120, Product code: HKI)
Predicate devices:	1. WELCH ALLYN 11810 OPTHALMOSCOPE (510(k) number: K003376, Product code: HLI) 2. KOWA GENESIS-D hand-held retinal camera (510(k) number: K080681, Product code: HKI)

Device description, Intended use & Effectiveness:

Optomed Smartscope M3-1 EY1 is a hand-held digital ophthalmoscope used to capture digital images and video of the cornea, aqueous, lens, vitreous and retina of the human eye. M3-1 EY1 has a LED light source. Image data is stored on the Flash memory card using 6.6 megapixel CMOS sensor and transferred to the PC by using USB connection. Device has rechargeable batteries.

Optomed Smartscope M3-1 EY1 and Kowa Genesis-D have similar indications for use, similar method of operation, and similar technological features such as; image capture method, data storage using SD card, LED for illumination, graphical user interface, USB cable, and display. Optomed Smartscope M3-1 EY1 and Welch Allyn Series 118 Ophthalmoscope have a similar kind of intended use, similar kind of modular configuration, similar radiation safety measures and similar performance in fundus examination. Table below gives a summary about comparison of the Optomed Smartscope M3-1 EY1 and the predicate devices.

	Optomed Smartscope M3-1 EY1	KOWA GENESIS-D	WELCH ALLYN 11800 OPTHALMOSCOPE
Intended use	to capture digital images and video of the cornea, aqueous, lens, vitreous and retina of the human eye.	to capture and save fundus images with mydriatic	to be used to examine the cornea, aqueous, lens, vitreous, and retina of the eye. It has the same operating principles and intended use as many competitive ophthalmoscopes already in commercial distribution.

Usage	Prescription use	Prescription use	Prescription use. Trained personnel within medical or school environment.
Use condition	With or without mydriatic.	With mydriatic.	With or without mydriatic.
Observation light source	Visible LED	Visible LED	Halogen lamp (visible light)
Observation	2.5" active matrix color TFT LCD	Visual observation 2.5" active matrix color TFT LCD for captured image observation	Visual observation
Photographing light source	Visible LED	Xenon flash lamp	-
Dioptre compensation	at least – 20 D to + 20 D	-15 D ~ +35 D	-20 D to + 20 D
Apertures	-	Multiple	Multiple
Picture angle	At least 25 degree	Horizontal 30 degree Vertical 25 degree	25 degree
Storage media	Flash memory card	Flash memory card	-
Camera specification	Color CMOS camera 6,600,000 pixels	Color CCD camera 2,000,000 pixels	-
Image data format	JPEG, MPEG-4	JPEG and uncompressed format	-
Weight	Camera unit: 0,5 kg	Camera unit: 1 kg	Ophthalmoscope with handle 0,35 kg
Power consumption	Battery 4.8V; Charging unit 44 VA	60 VA	Battery handle 3.5 V
Output terminals	USB (1.1) terminal (B-connector). Compatible with Windows® XP/VISTA.	USB (1.1) terminal (B-connector). Compatible with Windows® ME/2000/XP. Foot switch connection cable terminal.	-
Standards	IEC 60601-1:1988+A1+A2 IEC 60601-1-2:2001+A1 IEC 60601-1-4:2000 EN 60825-1:2001 +A1:2002+A2:2001 ISO 15004-2:2007	60601-1:1988+A1+A2 IEC 60825-1:1993+A1+A2	EN60601-1 IEC 60601-1-2 CAN/CSA-C22.2 No. 601.1-M90 UL 2601-1, Second Edition, 1997

General Equivalency comparison between Optomed Smartscope M3-1 EY1 and its predicates has been assessed by studying non-clinical performance data. Optical Equivalency and Radiation Safety measurements have been conducted as described in the FDA's Ophthalmoscope Guidance (Version 1.0, Issued on July 8, 1998) and Optomed Smartscope M3-1 EY1 has been found to be as safe as Welch Allyn Series 118 ophthalmoscope. In addition, a field of view comparison has been made and conclusion is, that field of view of the Optomed Smartscope M3-1 EY1 is similar or bigger than field of view of the Welch Allyn PanOptic Series 118 ophthalmoscope.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Optomed Oy
c/o Jeff D. Rongero
Reviewer, Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709-3995

OCT - 1 2009

Re: K092056
Trade/Device Name: Optomed Smartscope M3-1 EY1
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI
Dated: September 16, 2009
Received: September 18, 2009

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): K092056

Device Name: Optomed Smartscope M3-1 EY1

Indications for Use: Optomed Smartscope M3-1 EY1 digital ophthalmoscope is intended to capture digital images and video of the cornea, aqueous, lens, vitreous and retina of the human eye.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092056